

K000172

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SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM: DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988

510(k) CONTACT: Cheryl Hastings
Director, Regulatory Affairs

TRADE NAME: DePuy Contour Unicompartmental Knee Prosthesis

COMMON NAME: Unicompartmental Knee Prosthesis

CLASSIFICATION: 888.3530 Knee joint, femorotibial metal/polymer
semi-constrained cemented prosthesis

DEVICE PRODUCT CODE: 87 HRY

**SUBSTANTIALLY EQUIVALENT
DEVICES:** P.F.C. Σ Uni-compartmental Knee System (K954481)

DEVICE DESCRIPTION AND INTENDED USE:

The Contour Unicompartmental Knee Prosthesis femoral components are manufactured from cast Co-Cr-Mo alloy conforming to ASTM F-75. The articular surface is a sagittal "J" curve with a coronal radius. The fixation surface has one fixation peg and a central anterior/posterior (A/P) web. The Contour Unicompartmental Knee Prosthesis femoral components are available in sizes 2 and 3 and are designed for use with the P.F.C. Σ Unicompartmental tibial components, cleared in K954481.

The major differences between the P.F.C. Σ Unicompartmental femoral components and the Contour Unicompartmental femoral components are: the P.F.C. Σ femoral components have a symmetrical coronal cross-section while the Contour femoral components do not; the internal distal surface of the Contour femoral component is more sculpted than that of the P.F.C. Σ femoral component; the P.F.C. Σ femoral component has two fixation pegs while the Contour femoral component has one fixation peg and a central A/P web; and the P.F.C. Σ femoral component is available in sizes 2-6 with A/P dimensions ranging from 44 to 56mm. The Contour femoral component is available in sizes 2 and 3 with A/P dimensions of 48 and 52mm.

The DePuy Contour Unicompartmental Knee Prosthesis is indicated for use as the femoral component in a unicompartmental knee replacement for patients suffering from severe pain and disability due to structural damage caused by advanced femoral-tibial unicompartmental degenerative arthritis resulting from primary osteoarthritis or trauma. The device is also indicated for use in patients with osteochondritis dissecans of the femoral condyle. The system is indicated for use only with bone cement.

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BASIS OF SUBSTANTIAL EQUIVALENCE:

The Contour Unicompartmental Knee femoral components have the following similarities to the P.F.C. Σ Unicompartmental femoral components that were cleared in K954481. They have the same intended use, same material, same method of manufacture, similar designs, same mating components and the same sterilization and packaging methods. DePuy is making the described minor design modifications to improve the match with the femoral bone and to conserve bone stock.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2000

Ms. Cheryl K. Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K000172

Trade Name: DePuy Contour Unicompartmental Knee Prosthesis
Regulatory Class: II
Product Code: HRY
Dated: January 13, 2000
Received: January 20, 2000

Dear Ms. Hastings:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

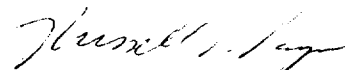
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


84 James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K000172

Device Name DePuy Contour Unicompartmental Knee Prosthesis

Indications for Use:


The DePuy Contour Unicompartmental Knee Prosthesis is indicated for use as the femoral component in a unicompartmental knee replacement for patients suffering from severe pain and disability due to structural damage caused by advanced femoral-tibial unicompartmental degenerative arthritis resulting from primary osteoarthritis or trauma. The device is also indicated for use in patients with osteochondritis dissecans of the femoral condyle. The system is indicated for use only with bone cement.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____


(Division Sign-Off)
Division of General Restorative Devices
51 (k) Number K000172

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